

1 THE HONORABLE THOMAS S. ZILLY

2
3
4
5
6
7
8 UNITED STATES DISTRICT COURT
9 FOR THE WESTERN DISTRICT OF WASHINGTON
10 AT SEATTLE

11 SIMULAB CORPORATION, a Washington
12 corporation,

13 Plaintiff,

14 vs.

15 SYNBONE AG, a Swiss corporation,

16 Defendant.
17

No. C07-1416Z

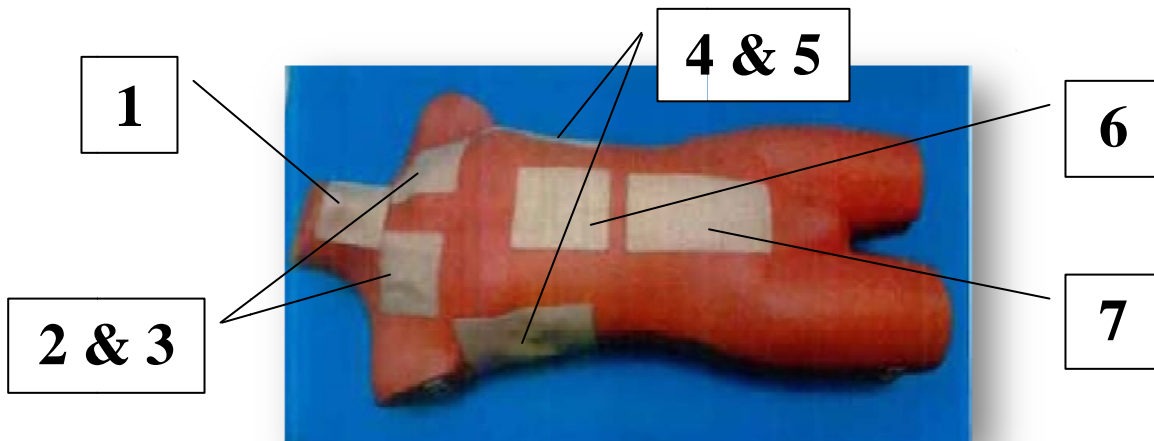
ORDER

18
19
20 THIS MATTER comes before the Court on defendant's motion for summary
21 judgment, docket no. 26. Having reviewed all papers filed in support of and in
22 opposition to the motion, and having heard the oral arguments of counsel, the Court
23 GRANTS the motion IN PART and DENIES the motion IN PART.
24
25
26

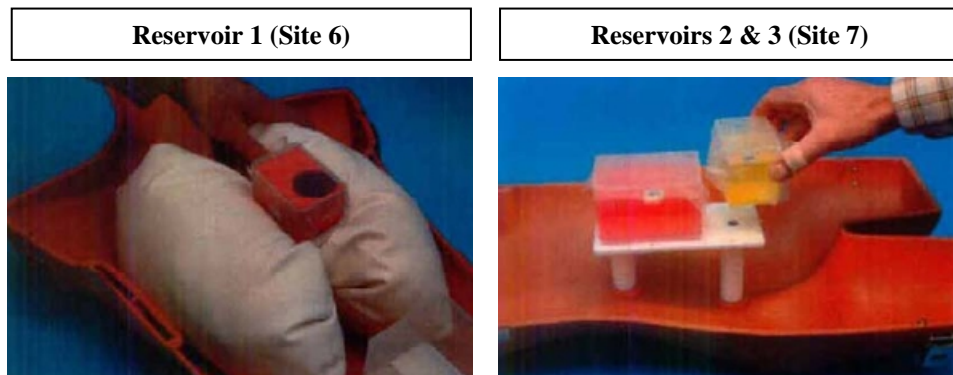
Background

Plaintiff Simulab Corporation (“Simulab”) owns U.S. Patent No. 6,780,016 (“the ’016 Patent”), which discloses a “surgical trainer having a simulated human tissue structure.” Simulab manufactures and sells a surgical trainer under the registered trademark “TraumaMan.” Synbone AG (“Synbone”), a Swiss corporation, manufactures and sells a product known as “SYNMAN.” In this action, Simulab alleges that the SYNMAN infringes Claims 1, 2, 3, 4, 37, and 43 of the ’016 Patent.

The SYNMAN is a device resembling a human torso. It facilitates training on certain emergency surgical procedures like cricothyroidotomy (a method for restoring an airway in the event of blockage due to neck trauma, burn inhalation, or allergic reaction), pericardiocentesis (a method for removing fluid from the pericardial sac, which is the tissue covering the heart), and peritoneal lavage (a method for washing out the abdominal cavity). *See* Synbone Manual at 1, Exh. A to Parkel Decl. (docket no. 27-2 at 2). The SYNMAN has seven sites containing replaceable simulated human tissue structures:



See id. The SYNMAN is comprised of a top half and a bottom half, which may be separated from one another by unhinging the clasps holding them together. Id. The bottom half has three reservoirs, which are fastened with Velcro to platforms mounted to the interior of the bottom half. Id. at 1-3 (docket no. 27-2 at 2-4). Reservoir 1 is in the upper portion of the torso and is situated between two inflatable structures (balloons) that simulate lungs. Id. at 1, 7 (docket no. 27-2 at 2, 8). Reservoirs 2 and 3 are in the middle portion of the torso; they are situated adjacent to each other and are mounted to a shared platform. Id. at 1, 2-3 (docket no. 27-2 at 2, 3-4).



See id. at 3 & 7 (docket no. 27-2 at 4 & 8).

To prepare the SYNMAN for use, the reservoirs are filled with colored liquids. Both Reservoir 1, which contains a non-absorbent sponge having a partially-open cylindrical cavity, and Reservoir 2 are filled with red liquid, while Reservoir 3 is filled with yellow liquid. Id. at 1-3 (docket no. 27-2 at 2-4). All three reservoirs are then covered with a thin plastic, self-adhesive film. Id.

Various pads are installed at all but one of the seven sites containing simulated human tissue structures. At Sites 2, 3, and 6, the pads are on the interior side of the

1 top half of the SYNMAN, secured by plates held in place by set screws. *Id.* at 4-5
2 (docket no. 27-2 at 5-6). At Sites 4 and 5, the pads, containing rigid strips simulating
3 human ribs, fit into grooves along the sides of the top and bottom halves of the
4 SYNMAN. *Id.* at 8 (docket no. 27-2 at 9). At Site 7, the pad sits on the exterior side
5 of the top half of the SYNMAN. *Id.* at 6 (docket no. 27-2 at 7). Each of the pads is
6 covered with simulated skin, held in place with Velcro. *Id.* at 4-9 (docket no. 27-2 at
7 5-10). In contrast, at Site 1, no pad is present. Rather, at Site 1, a simulated cricoid
8 (the ring of cartilage around the trachea), which is molded of polyurethane rubber, is
9 inserted into a receptacle on the exterior of the top half of the SYNMAN and then
10 covered with simulated skin. *Id.* at 7 (docket no. 27-2 at 8); *see also* Parkel Decl. at
11 ¶ 53 (docket no. 27).

14 In its motion for summary judgment, Synbone contends that each of the seven
15 simulated human tissue structure sites of the SYNMAN is missing at least one of the
16 limitations of each of the claims allegedly infringed. At oral argument, Simulab
17 conceded that not all of the sites of the SYNMAN infringe the '016 Patent; rather, only
18 four of the sites remain at issue. In particular, Simulab clarified that (i) only Site 6 is
19 alleged to infringe Claims 1-4, (ii) only Site 7 is alleged to infringe Claim 37, and
20 (iii) only Sites 4, 5, and 7 are alleged to infringe Claim 43. This Order will discuss
21 each of these contentions seriatim; however, in light of Simulab's concession at oral
22 argument, any other claims of infringement are hereby DISMISSED.
23
24
25
26

1 **Discussion**

2 **A. Summary Judgment Standard**

3 The Court should grant summary judgment if no genuine issue of material fact
4 exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P.
5 56(c). The moving party bears the initial burden of demonstrating the absence of a
6 genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). A
7 fact is material if it might affect the outcome of the suit under the governing law.
8 Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In support of its motion
9 for summary judgment, the moving party need not negate the opponent's claim,
10 Celotex, 477 U.S. at 323; rather, the moving party will be entitled to judgment if the
11 evidence is not sufficient for a jury to return a verdict in favor of the opponent,
12 Anderson, 477 U.S. at 249.

13 When a properly supported motion for summary judgment has been presented,
14 the adverse party "may not rely merely on allegations or denials in its own pleading."
15 Fed. R. Civ. P. 56(e)(2). Rather, the non-moving party must set forth "specific facts"
16 demonstrating the existence of a genuine issue for trial. Id.; Anderson, 477 U.S. at
17 256. To survive a motion for summary judgment, the adverse party must present
18 affirmative evidence, which "is to be believed" and from which all "justifiable
19 inferences" are to be favorably drawn. Anderson, 477 U.S. at 255, 257. When the
20 record, however, taken as a whole, could not lead a rational trier of fact to find for the
21 non-moving party, summary judgment is warranted. See Miller v. Glenn Miller Prod.,

1 *Inc.*, 454 F.3d 975, 988 (9th Cir. 2006); *see also Beard v. Banks*, 548 U.S. 521, 529
2 (2006) (“Rule 56(c) ‘mandates the entry of summary judgment, after adequate time for
3 discovery and upon motion, against a party who fails to make a showing sufficient to
4 establish the existence of an element essential to that party’s case, and on which that
5 party will bear the burden of proof at trial.’” (quoting *Celotex*, 477 U.S. at 322)).
6

7 **B. Patent Infringement**

8 Analysis of a patent infringement claim requires two steps. First, the claims of
9 the patent must be properly construed to determine their scope and meaning.
10

11 *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1341 (Fed. Cir. 2001). Second,
12 the properly construed claims must be compared to the accused device or process. *Id.*
13 Infringement exists if the standards of either literalism or the doctrine of equivalents
14 are met. *See General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 984 (Fed. Cir.
15 1997). Literalism requires that every limitation of the patent claim at issue be found in
16 the accused device or process. *Id.* at 981. The doctrine of equivalents can be satisfied
17 in two alternative ways: (i) if the differences between a claim limitation and an
18 element in the accused device or process are insubstantial; or (ii) if the element in the
19 accused device or process “performs substantially the same function in substantially
20 the same way to obtain substantially the same result” as the claim limitation. *Voda v.*
21 *Cordis Corp.*, 536 F.3d 1311, 1326 (Fed. Cir. 2008). A determination of infringement
22 constitutes a question of fact, and summary judgment of non-infringement may be
23 granted only if, after viewing the alleged facts in the light most favorable to the non-
24
25
26

1 movant, no genuine issue exists concerning whether the accused device or process is
2 encompassed by the claims. *Hilgraeve*, 265 F.3d at 1341.

3
4 **C. Infringement Analysis**

5 **1. Claims 1, 2, 3, and 4**

6 With respect to Claim 1 and its dependent claims, namely Claims 2, 3, and 4,
7 Synbone contends that Site 6 of the SYNMAN is missing a “plurality of integral fluid
8 channels.” Claim 1 of the ’016 Patent discloses:

9 A surgical trainer, comprising:

10 a simulated human tissue structure, comprising:

11
12 at least one simulated membranous layer comprising at
13 least one elastomeric layer reinforced by at least one
14 fibrous layer; and

15 at least one simulated sub-membranous layer comprising at
16 least one elastomeric layer underlying a first
17 membranous layer, wherein at least one of said at least
18 one simulated membranous layer and said at least one
19 simulated sub-membranous layer has a *plurality of*
20 *integral fluid channels*, a material comprising said at
least one of said at least one simulated membranous
layer and said at least one simulated sub-membranous
layer defining walls of the *plurality of integral fluid*
channels.

21 ’016 Patent, Col. 13 at 13-26, Exh. 1 to Prehearing Statement (docket no. 16-3 at 18)
22 (emphasis added). The Court has previously construed the term “integral fluid
23 channels” to mean “pathways capable of containing fluid that are formed of the
24 surrounding material.” Order at 17 (docket no. 24).

1 At Site 6 of the SYNMAN, fluid is contained within a rigid plastic reservoir,
2 into which a non-absorbent sponge having a partially-open cylindrical cavity is
3 placed,¹ and over which a thin plastic film is draped. Simulab contends that the
4 partially-open cylindrical cavity and the interstices between the walls of the plastic
5 reservoir and the walls of the non-absorbent sponge constitute a “plurality of integral
6 fluid channels” because they are capable of containing fluid and are formed of the
7 surrounding material. In its briefing, Simulab misconstrued the Court’s Markman
8 Order as not restricting “surrounding material” to the simulated membranous or
9 simulated sub-membranous layers described in Claim 1. Simulab argued that the
10 Court “rejected” Synbone’s contention that integral fluid channels can exist only
11 within membranous or sub-membranous layers. See Response at 11 (docket no. 28).

14 Simulab, however, misread the Court’s Markman Order, in which the Court
15 concluded: “Claim 1 indicates that both a membranous layer and a sub-membranous
16 layer will include a plurality of ‘integral fluid channels,’ the walls of which are defined
17 by the respective layers.” Order at 16 (docket no. 24). Because the claim language
18 itself defined the location of, or the material surrounding, the integral fluid channels,
19 the Court found Synbone’s proposed construction, defining an integral fluid channel as
20 contained within or provided in a simulated membranous or simulated sub-
21 membranous layer, to be “unnecessarily duplicative.” Id. Nothing in the Court’s

24
25 ¹ Simulab asserts that the sponge simulates the muscles of the heart. To the extent that the sponge
26 simulates a portion of an internal organ, namely the heart, it cannot infringe any of the claims of the
’016 Patent because methods for making simulated internal organs were explicitly disclaimed therein.
See Order at 13-14, 16 (docket no. 24).

1 Markman Order supports Simulab’s inference that the walls of the integral fluid
2 channels may be comprised of other than a simulated membranous or sub-
3 membranous layer, and such contention runs contrary to both the rules of grammar and
4 the canons of patent claim construction.²

6 **a. Site 6 Lacks Channels With Membranous Walls**

7 To the extent that a “fluid channel” exists at Site 6, Simulab agreed during oral
8 argument that the rigid plastic container labeled as Reservoir 1 comprises a wall of
9 such “fluid channel.” Simulab, however, has proffered no evidence that the rigid
10 container labeled as Reservoir 1 constitutes a simulated membranous or sub-
11 membranous layer, or an equivalent thereof. For purposes of Claim 1, both a
12 simulated membranous and a simulated sub-membranous layer must contain at least
13 one elastomeric layer. The Court has construed the term “elastomeric layer” to mean
14 “a layer formed of a material that is capable of recovering size and shape after
15 deformation.” Order at 9 (docket no. 24). Reservoir 1 is a rigid container having no
16 elastomeric properties and therefore does not qualify as a simulated membranous or
17 sub-membranous layer. Simulab conceded this fact during oral argument. Thus,
18 although the fluid channel at Site 6 is formed of the surrounding material, the
19
20
21

22 ² At oral argument, Simulab appeared to retreat from its earlier position, and instead asserted that the
23 thin film covering Reservoir 1 constitutes a membranous layer, that the non-absorbent sponge
24 constitutes a sub-membranous layer, and that the walls of the fluid channel at Site 6 are therefore
25 composed of membranous and sub-membranous layers. Simulab’s recast contention is equally lacking
26 in merit. Contrary to Simulab’s assertion, the thin film covering Reservoir 1 does not form a wall of
any “fluid channel” because it does not in any way restrain the liquid in the rigid container. Assuming
that Reservoir 1 remains oriented in its usual, upright position, the thin film can be removed from the
top of Reservoir 1 without causing the fluid to drain or flow out of the container. Thus, the thin film
does not constitute a membranous layer in which a fluid channel exists.

1 surrounding material does not have the requisite qualities of a simulated membranous
2 or sub-membranous layer, and the pathway for liquid at Site 6 is not an “integral fluid
3 channel” within the meaning of Claim 1 and its dependent claims.³
4

5 **b. Site 6 Lacks Plurality of Fluid Channels**

6 In addition, the rigid reservoir and non-absorbing sponge at Site 6 do not form
7 more than one fluid channel, and therefore, they do not satisfy the “plurality”
8 requirement of Claim 1. The parties did not ask the Court to construe the term
9 “plurality,” which has the ordinary meaning of “being numerous” or “a large number
10 or quantity,” *see* Webster’s Third New Int’l Dictionary at 1745 (1981) [“Webster’s”],
11 but both parties have employed the common definition, describing the plurality of
12

13
14 ³ During oral argument, Simulab referred to the doctrine of equivalents, but failed in both its oral
15 presentation and its briefing to explain how the differences between Site 6 and the “integral fluid
16 channel” limitation of Claim 1 are insubstantial or how Site 6 “performs substantially the same
17 function in substantially the same way to obtain substantially the same result” as the “integral fluid
18 channel” limitation. *See Voda*, 536 F.3d at 1326. Moreover, Simulab’s ability to assert the doctrine of
19 equivalents is restricted by the prosecution history relating to Claim 1. Prosecution history estoppel
20 applies if the applicant made a narrowing amendment to the claim at issue or if the applicant
21 surrendered claim scope through argument to the patent examiner. *Id.* at 1325. While the doctrine of
22 equivalents is premised on language’s inability to fully “capture the essence of the innovation,”
23 prosecution history estoppel is based on evidence that the inventor focused on the subject at hand,
24 “knew the words for both the broader and narrower claim, and affirmatively chose the latter.” *Festo*
25 *Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734-35 (2002). Here, in connection
26 with an amendment to Claim 1, the following argument was submitted to the U.S. Patent and
Trademark Office as to why the invention was not obvious in light of prior art, namely U.S. Patent
No. 5,775,916 (“Cooper”): “While Cooper discloses fluid channels in his invention, Cooper teaches
that such channels are formed separately as tubes of latex material that are incorporated into a
layer Thus, according to Cooper the material comprising the walls of the channel is not the
material comprising the layer. Applicant has determined that integral channels filled with fluid
provide a much more realistic tactile experience when an incision is made into a simulated tissue layer
containing such integral fluid channels” Amendment and Request for Reconsideration at 6,
Exh. 2 to Prehearing Statement (docket no. 16-4 at 7). This prosecution history evidences the
surrender of equivalents using a material other than the membranous or sub-membranous layer to form
or partially form the walls of a channel. Thus, Simulab is estopped from asserting that a rigid, non-
elastomeric container enclosing a column of liquid is equivalent to an “integral fluid channel” within
the meaning of Claim 1 and its dependent claims.

1 integral fluid channels as simulating human veins or arteries, thereby implying the
2 existence of more than one such pathway. See Joint Claim Chart at 8 (docket no. 16-
3 2). Contrary to Simulab’s contention, the reservoir and sponge at Site 6 create only
4 one continuous volume of fluid. Simulab’s attempt to divide the liquid into seven
5 portions, namely the column of fluid inside the cavity of the sponge (channel 1), the
6 thin layer of liquid between the sponge and each of the sides of the rigid container
7 (channels 2-5), and the small amount of fluid underneath and above the sponge
8 (channels 6-7), defies both scientific principles and common sense. Due to the
9 inherent properties of liquids, any fluid poured into the reservoir will flow into and fill
10 the interstices between it and the sponge, without any gaps or breaks, forming one
11 uninterrupted channel. Thus, Site 6 does not satisfy the requirement of Claim 1 that at
12 least one membranous and at least one sub-membranous layer contain a “plurality” of
13 integral fluid channels.⁴
14
15
16
17
18
19

20 ⁴ Simulab raised for the first time at oral argument the contention that “capillary action” in the sponge
21 satisfies the requirement of a “plurality of integral fluid channels.” Simulab subsequently submitted
22 briefing on the issue, which the Court has considered. Notably, however, Simulab has provided no
23 evidence to corroborate its “capillary action” theory, which contradicts Synbone’s description of the
24 sponge as “closed-cell” and “non-fluid absorbing.” See Reply at 5 (docket no. 32). Moreover,
25 Simulab’s new argument meets only a portion of the limitation in Claim 1. Claim 1 requires, at a
26 minimum, that both a membranous layer and a sub-membranous layer have a “plurality of integral
fluid channels.” See ’016 Patent, Col. 13 at 19-22 (docket no. 16-3 at 18). The parties agree that the
sponge constitutes at best only a sub-membranous layer. Thus, even if the sponge “retains liquid,” see
Suppl. Response at 1 (docket no. 37), the requisite membranous layer containing two or more fluid
channels is still missing. Thus, the Court rejects Simulab’s “capillary action” hypothesis as untimely,
unsupported by the record, and futile.

1 For the foregoing reasons, the Court GRANTS partial summary judgment in
2 favor of Synbone and DISMISSES Simulab's allegations of infringement as to
3 Claim 1 and its dependent claims, namely Claims 2, 3, and 4 of the '016 Patent.
4

5 **2. Claim 37**

6 Claim 37 requires that at least one replaceable, incisable simulated human
7 tissue structure covering an opening adjacent to a simulated internal anatomical
8 structure contain a plurality of simulated membranous layers and a plurality of
9 simulated sub-membranous layers. '016 Patent, Col. 16 at 18-34 (docket no. 16-3 at
10 19). In the simulated human tissue structure described by Claim 37, each of the
11 simulated membranous layers must be denser than, thinner than, and harder to dissect⁵
12 than any simulated sub-membranous layer. Col. 16 at 34-40. In addition, the
13 simulated structure at issue must include:
14

15 a first composite layer corresponding to a simulated membranous layer,
16 said first composite layer comprising at least one elastomeric layer
17 reinforced by at least one fibrous layer;
18

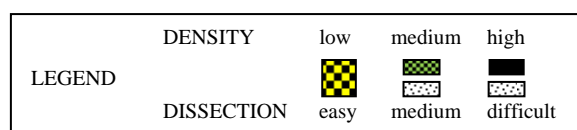
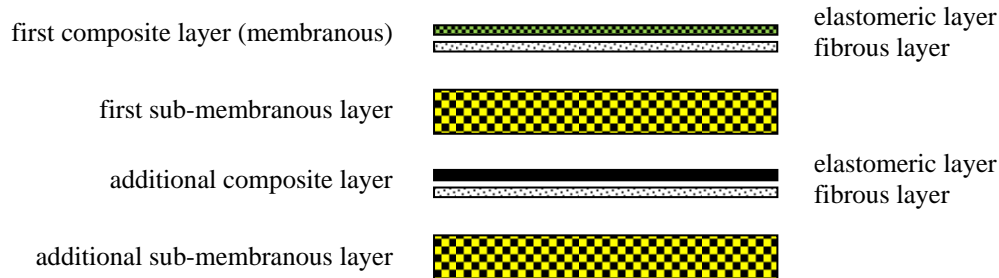
19 ⁵ In his declaration, Christopher Toly, the inventor named in the '016 Patent, posits that "[t]o simulate
20 surgical dissection effectively, the layers of simulated tissue must remain 'stacked' or intact to a
21 reasonable degree" and that "[t]he 'dissection' of each descending layer gets harder to complete as it is
22 mostly concealed and hard to reach through the upper tissue layers." Toly Decl. at ¶ 11 (docket
23 no. 30). Mr. Toly contends that skin dissection is easier than dissection of the underlying layers
24 because the skin is "in clear view with no obstructions" and "unattached to other layers." *Id.*
25 Visibility, however, is not the gauge by which Claim 37 requires that ease of dissection be evaluated.
26 Claim 37 draws a correlation between the density of the material and its relative ease of dissection.
The first sub-membranous layer is required to include an elastomeric layer of lower density "such
that" it "can readily be dissected using a blunt object," and the additional composite layer must have
an elastomeric layer of higher density "such that" the resulting composite layer "is relatively harder to
dissect than the first simulated membranous layer." Col. 16 at 50-54, 60-65 (docket no. 16-3 at 19);
see also Webster's at 2283 ("such" means "having a quality to a degree to be indicated" as in "his joy
at seeing her was ~ that he wept"). Thus, for purposes of the claims at issue, the inherent properties of
the layers, reflected in the measure of their density, and not their location within the "stack,"
correspond to the relative ease or difficulty with which they are dissected.

1 a first simulated sub-membranous layer disposed below said first
2 composite layer, said first simulated sub-membranous layer
3 comprising at least one elastomeric layer, wherein each elastomeric
4 layer of the first simulated sub-membranous layer has a lower
5 density than any elastomeric layer of the first composite layer, such
6 that said first simulated sub-membranous layer can readily be
7 dissected using a blunt object;

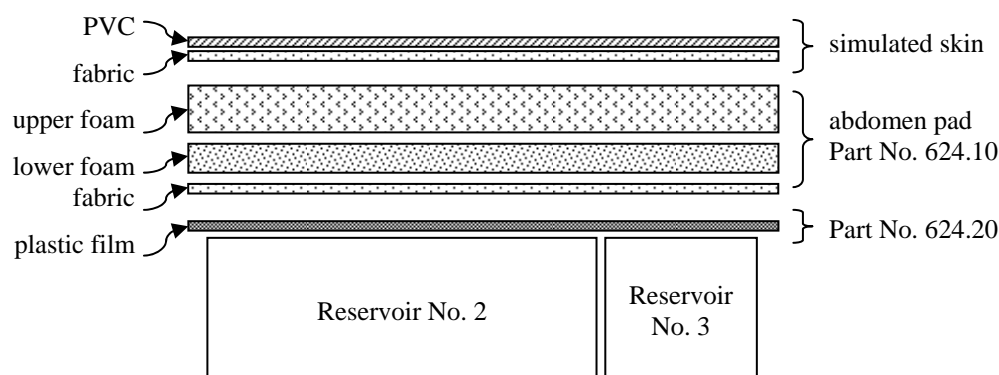
8 at least one additional composite layer corresponding to a simulated
9 membranous layer disposed below said first simulated sub-
10 membranous layer and comprising at least one elastomeric layer,
11 reinforced by at least one fibrous layer, wherein each elastomeric
12 layer of the at least one additional composite layer has a higher
13 density than any elastomeric layer of the first composite layer, such
14 that each additional composite layer corresponding to a simulated
15 membranous layer is relatively harder to dissect than the first
16 simulated membranous layer; and

17 at least one additional simulated sub-membranous layer disposed below
18 said first simulated sub-membranous layer and comprising at least
19 one elastomeric layer, wherein each elastomeric layer of the at least
20 one additional simulated sub-membranous layer has a lower density
21 than any elastomeric layer of the first composite layer.

22 Col. 16 at 42 – Col. 17 at 5 (docket no. 16-3 at 19-20). Claim 37 does not specify
23 whether the “at least one additional composite layer” is disposed above or below the
24 “at least one additional simulated sub-membranous layer,” and therefore, at least two
25 alternative stratifications are possible. In either configuration, however, the
26 elastomeric layer of any additional composite layer must be denser and harder to
dissect than the elastomeric layer of the top or first composite layer. Thus, regardless
of the order of the lower two or more strata, the various layers must have the following
density and ease of dissection characteristics:



The parties agree that the only portion of the SYNMAN that might infringe Claim 37 is Site 7, which includes an “abdomen pad.” At Site 7, the components are stacked as follows:



The simulated skin (*i.e.*, polyvinyl chloride (“PVC”) bonded to fabric) and the upper foam layer of the abdomen pad located at Site 7 of the SYNMAN correspond respectively to the first composite (membranous) and first sub-membranous layers of Claim 37. In its briefing, Simulab drew a correlation between the lower foam and fabric layers of the abdomen pad and the additional composite layer of Claim 37. At oral argument, however, Simulab conceded that the lower foam (elastomeric) layer of

1 the abdomen pad is less dense than the PVC (elastomeric) layer of the simulated skin.⁶
2 Such relationship runs opposite to the one required in Claim 37. As a consequence,
3 Simulab changed its position, instead contending that the plastic film covering
4 Reservoirs 2 and 3 constitutes the requisite elastomeric layer having a higher density
5 than the PVC of the simulated skin.
6

7 As an initial matter, the Court notes that Simulab has not provided any density
8 or tensile strength data regarding the layers at issue. Moreover, by altering its
9 infringement contention at the eleventh hour, Simulab has thwarted Synbone's ability
10 to respond with meaningful expert opinion or other evidence. The Court does not
11 countenance these tactics. Nevertheless, the Court has considered Simulab's newest
12 argument and has found it wanting. Claim 37 requires that any additional composite
13 layers contain, at a minimum, an elastomeric layer reinforced by a fibrous layer. The
14 parties asked the Court to construe the term "composite layer," which the Court
15 concluded is "a layer formed of two or more distinct parts that may or may not be
16 bonded together," Order at 7 (docket no. 24), but the parties did not seek an
17 interpretation of the word "reinforce" or the phrase "reinforced by." Now, Simulab's
18 contention, namely that the fabric underside of the abdomen pad constitutes the fibrous
19 layer, and the plastic film overlying the reservoirs constitutes the elastomeric layer, of
20
21
22
23

24 ⁶ In its motion papers, Synbone provided evidence that the composite layer comprised of the lower
25 foam and fabric in the abdomen pad is easier to dissect than the simulated skin at Site 7, which is
26 contrary to the limitation of Claim 37. *See* Parkel Decl. at ¶ 47 (docket no. 27) ("It is much more
difficult to dissect Replacement Part PRO624.11S (Skin, Abdomen) than it is to dissect the lower
density PE foam and thin fabric of Replacement Part PRO624.10 (Pad, Abdomen)."). Simulab does
not dispute this fact.

1 the additional composite layer required by Claim 37, requires the Court to ascertain the
2 meaning of the term “reinforced” as used in the claim language “at least one
3 elastomeric layer, reinforced by at least one fibrous layer.” Col. 16 at 58-59 (docket
4 no. 16-3 at 19).

5
6 In construing the meaning of patent claim language, the Court must consider
7 the intrinsic evidence in the record, namely the claims themselves, the specification,
8 and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979
9 (Fed. Cir. 1995). The words of a claim are generally assigned their “ordinary and
10 customary meaning.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005).
11 The ordinary and customary meaning of a claim term is the definition ascribed to it by
12 “a person of ordinary skill in the art in question at the time of the invention.” *Id.* at
13 1313. Claim language must also be read in light of the specification. *Markman*, 52
14 F.3d at 979. If the specification reveals a definition given to a claim term that differs
15 from the meaning it would otherwise possess, the inventor’s lexicography trumps the
16 ordinary and customary, or dictionary, construction. *Phillips*, 415 F.3d at 1316.

17
18
19 The common definition of “reinforce” is “to strengthen with additional force,
20 assistance, material, or support” or to “make stronger.” Webster’s at 1915. The
21 specification does not reveal a contrary interpretation, but rather compels a similar
22 construction. In describing the method for creating a composite layer, the
23 specification indicates that a fibrous layer may be “applied below or atop an uncured
24 silicone formulation while in the mold” so “as the silicone formulation cures,” the
25
26

1 “fibrous layer is bonded thereto,” or that the fibrous layer can be a non-bonded layer
2 adjacent to a “silicone blend” layer. Col. 5 at 37-41, Col. 6 at 18-22 (docket no. 16-3
3 at 14). Silicone is an elastomeric material. Col. 5 at 33-35. According to the
4 specification, the fibrous layer “imparts a realistic resistance to cutting.” Col. 5 at 42.
5 Thus, the specification indicates that the fibrous layer, regardless of whether it is
6 bonded to the adjacent layer, functions as a material that strengthens the elastomeric
7 layer.
8

9
10 At Site 7 of the SYNMAN, a significant gap separates the fabric of the
11 abdomen pad (the fibrous layer) and the plastic film covering the reservoirs (the
12 elastomeric layer alleged to have higher density than the PVC layer of the simulated
13 skin). The abdomen pad sits above a rectangular, partially-open receptacle on the
14 exterior of the top half of the SYNMAN, while the plastic film adhered to the
15 reservoirs is some distance below the interior of the top half of the SYNMAN.
16 Simulab fails to explain how, given the space between the layers, the fabric of the
17 abdomen pad serves in any way to strengthen or “reinforce” the plastic film.
18 Moreover, Simulab does not make the necessary comparison. Even if the plastic film
19 is denser than the PVC, Simulab has proffered no evidence or argument that the thin
20 plastic film in combination with the virtually translucent fabric of the abdomen pad is
21 more difficult to dissect than the thicker, heavier simulated skin, as required by
22 Claim 37. Although Synbone ordinarily would bear the burden of producing evidence
23 in connection with a motion for summary judgment, because Simulab failed to timely
24
25
26

1 articulate its “plastic film” infringement contention, the onus was on Simulab, and not
2 Synbone, to present a supporting affidavit or declaration.

3
4 For the foregoing reasons, the Court GRANTS partial summary judgment in
5 favor of Synbone and DISMISSES Simulab’s allegation of infringement as to
6 Claim 37 of the ’016 Patent.

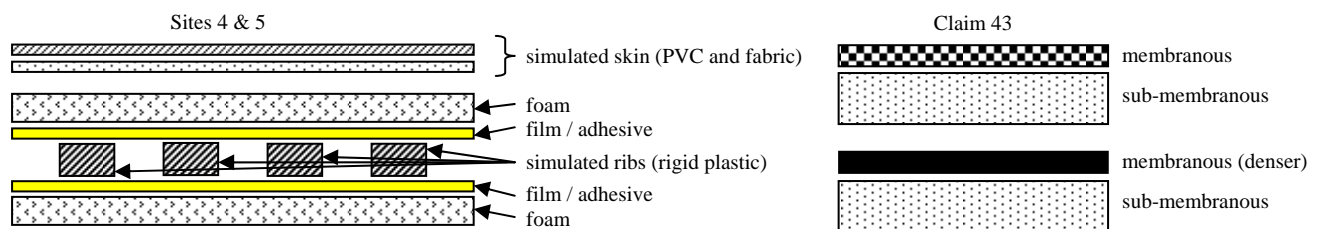
7 **3. Claim 43**

8 Like Claim 37, Claim 43 requires that the incisable simulated human tissue
9 structure at issue contain a plurality of simulated membranous layers and a plurality of
10 simulated sub-membranous layers.⁷ Col. 20 at 49-51 (docket no. 16-3 at 21). In
11 addition, each of the simulated membranous layers must be denser than, thinner than,
12 and harder to dissect than any simulated sub-membranous layer. Col. 20 at 51-57.
13 Claim 43, however, differs from Claim 37 in the following ways. First, at least one of
14 the simulated sub-membranous layers described in Claim 43 must be “readily
15 dissected using a blunt object.” Col. 20 at 57-58. Second, Claim 43 requires that “a
16 membranous layer disposed at a top of said incisable simulated human tissue
17 structure” be “less dense and relatively easier to dissect than each other membranous
18 layer.” Col. 20 at 58-61. Finally, “the plurality of simulated membranous layers and
19 simulated sub-membranous layers” in Claim 43 must be “disposed such that at least
20
21
22

23 ⁷ As mentioned earlier, at the Markman stage, the parties did not ask the Court to interpret the term
24 “plurality,” but they have used it in a manner consistent with its ordinary and patent law meaning,
25 namely a quantity of two or more. *See Cybersettle, Inc. v. Nat’l Arbitration Forum, Inc.*, 243 Fed.
26 Appx. 603, 606 (Fed. Cir. 2007) (At oral argument, counsel agreed that “the claim term ‘plurality’
refers to two or more of something. That definition is consistent with the well understood meaning of
the term ‘plurality’ both in general and in patent parlance.”). Thus, Claim 43 requires the presence of
two or more simulated membranous layers and two or more simulated sub-membranous layers.

one simulated membranous layer is adjacent to at least one simulated sub-membranous layer.” Col. 20 at 61-65.

Claim 43 does not specify whether a membranous layer is disposed above or below its adjacent sub-membranous layer, and therefore, five alternative stratifications of the at least four layers are possible. In addition, Claim 43 does not indicate which of the sub-membranous layers must be “readily dissected using a blunt object,” and thus, two options exist for each of the five potential arrangements of layers. With regard to Sites 4, 5, and 7, which are the only portions of the SYNMAN that Simulab alleges infringe Claim 43, only one of the ten alternatives has relevance. Site 7 has already been described. Sites 4 and 5 both have the following components, which are compared in the following illustration against the relevant requirements of Claim 43:



Notably, Simulab does not argue that the simulated ribs are membranous layers. Although the ribs are, as required by Claim 43, denser and more difficult to dissect than the simulated skin layer (“a top” membranous layer), they are also thicker than the foam layers and thereby fail to satisfy the limitation of Claim 43 that they be thinner than any sub-membranous layer. Instead, Simulab contends that the film or adhesive layers, which serve to bond the simulated ribs between the upper and lower

1 foam layers, constitute membranous layers. Neither party proffered any evidence
2 comparing these particular layers, and the Court must conclude that a genuine issue of
3 material fact remains as to Sites 4 and 5. Likewise, with respect to Site 7, neither party
4 has presented any data concerning whether the plastic film covering Reservoirs 2 and
5 3 is of higher density or is more difficult to dissect than the simulated skin layer.⁸ The
6 Court therefore DENIES WITHOUT PREJUDICE Synbone's motion for summary
7 judgment as to Claim 43 of the '016 Patent, with respect to Sites 4, 5, and 7 of the
8 SYNMAN.
9

10
11 Because the Court, however, remains skeptical that Simulab can demonstrate
12 the requisite layer properties and relationships, the Court DIRECTS Simulab to submit
13 an offer of proof within twenty (20) days of the date of this Order. If such offer of
14 proof fails to include admissible evidence that the adhesive layers of Sites 4 and 5 and
15 the film layer of Site 7 are denser and more difficult to dissect than the relevant
16 simulated skin layer, as those relationships have been defined in this Order, the Court
17 will grant partial or full summary judgment in favor of Synbone as to Claim 43.⁹
18
19

20 ⁸ The Court's independent examination of a sample SYNMAN and its components strongly suggests
21 that neither the adhesive layers of Sites 4 and 5 nor the film layer of Site 7 satisfy the limitation of
22 Claim 43 that they be denser and more difficult to dissect than the respective simulated skin layers.

23 ⁹ As an alternative basis for summary judgment, Synbone contends that Sites 4 and 5 also fail to
24 satisfy the limitations of Claim 43 because the foam in the rib structure is not "readily dissected using
25 a blunt object." Synbone argues that the appropriate measure is whether the foam can be divided or
26 separated "using a finger." Reply at 11 (docket no. 32). The "finger" standard, however, does not
appear in the Court's Markman Order, which delineated between the terms "dissect" ("divide or
separate into parts") and "incise" ("to cut with a knife"), and ultimately concluded that the phrase
"being readily dissected using a blunt object" means that "the specified layer must itself be easily cut
or separated without the aid of a sharp instrument, as opposed to being separable from another layer."
Order at 9-12 (docket no. 24). The Court declines to adopt the "finger" standard, which is not

1 **Conclusion**

2 For the foregoing reasons, partial summary judgment is GRANTED in favor of
3 Synbone, and Simulab's allegations of infringement as to Claims 1, 2, 3, 4, and 37 of
4 the '016 Patent are DISMISSED. Synbone's motion for summary judgment as to
5 Claim 43 of the '016 Patent is DENIED WITHOUT PREJUDICE as to Sites 4, 5, and
6 7 of the SYNMAN. All other infringement claims are DISMISSED.

8 Simulab is directed to file, within twenty (20) days of the date of this Order, an
9 offer of proof concerning the relevant properties, and comparative ease of dissection,
10 of the layers at issue in Sites 4, 5, and 7. Synbone shall not file any response unless
11 requested by the Court. The Court will request a joint status report for purposes of
12 selecting a trial date and crafting a scheduling order, if appropriate, after it reviews
13 Simulab's offer of proof.
14

15 ///

16 ///

17 ///

18 ///

19 ///

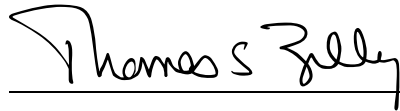
20 ///

21
22 supported by the prosecution history to which Synbone cites. *See* Sinana Decl. at ¶ 5 (docket no. 16-5
23 at 31) ("Once the initial incision is made, the surgeon will use his/her fingers or the blunt end of a
24 scalpel to move through the fat layer until a lower membranous layer (such as the anterior rectus
25 sheath) is exposed." (emphasis added)). Simulab has presented video footage that is sufficiently
26 probative of the ease with which the foam layers at issue can be dissected using a blunt object, *see*
Toly Decl. at Exhs. G & H (docket no. 30), and therefore, whether Sites 4 and 5 contain at least one
sub-membranous layer capable of being "readily dissected using a blunt object" constitutes a genuine
issue of material fact, which would preclude summary judgment unless Simulab fails to provide an
adequate offer of proof as directed above.

1 IT IS SO ORDERED.

2 The Clerk is directed to send a copy of this Order to all counsel of record.

3 DATED this 6th day of February, 2008.

4
5
6 

7
8 Thomas S. Zilly
9 United States District Judge
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26